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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,819	06/14/2007	Samuel K. Sia	H0498.70211US02	5917
86110	7590	09/01/2009		
Harvard University & Medical School c/o Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210-2206			EXAMINER YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			09/01/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,819	<b>Applicant(s)</b> SIA ET AL.	
	<b>Examiner</b> MELANIE YU	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45,46,48,51-53 and 72-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45,46,48,51-53 and 72-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendment filed 1 June 2009 has been entered.

### ***Status of the Claims***

2. Claims 45, 46, 48, 51-53 and 72-102 are currently pending in this application and examined on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 45, 46, 48, 51-53 and 72-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preambles of the claims are indefinite because the claims fail to describe what type of method is being performed. It is unclear whether the claims are drawn to a method of accumulating an opaque material or whether the claims are drawn to a method of detection of a sample component that binds with the binding partner disposed on the substrate. The claims are also lacking correlation because the purpose of the recited method steps is not described in the preamble of the claim.

2. Claims 45, 46, 48, 51-53 and 72-102 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: associating a metal colloid with the sample component-binding partner complex and detection of the opaque material to assay for the sample component. It is not clear what method is

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performed by accumulating an opaque material on a portion of the surface of the microfluidic channel. The relationship of the opaque material to the sample component is not clear in the claims, and according to the specification, a detection step cannot be performed without the presence of a metal colloid. According to the specification at page 4, lines 25-30, the opaque material requires a metal colloid that is associated with the sample component-binding partner complex in order to provide a catalytic surface for the deposition of the opaque material. The specification also teaches that the detection method requires a step of detecting the opaque material to determine the presence of the sample component. The specification at page 5, lines 5-6, teaches that the opaque material enhances the assay, but does not teach that the accumulation of the opaque material alone can provide a sufficient assay for detection of the sample component. The claims are rendered indefinite because the opaque material has no purpose without the presence of a metal colloid associated with the sample component-binding partner complex.

***Allowable Subject Matter***

3. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach allowing a sample component to bind with a binding partner disposed on the surface of a microfluidic channel and then flowing in series a first, second and third fluid, wherein the first and second fluids are separated by the third fluid that is immiscible with the first and second fluids.

4. Saros et al. (US 4,517,302) teach first and second fluid reagents in a microchannel separated by a third fluid (air), which is immiscible with the first and

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second fluid reagents, but do not teach flowing a fluid sample over a surface of the microchannel and allowing sample components to bind with a binding partner disposed on the surface or accumulating an opaque material on the microfluidic channel.

5. Kumar et al. (US 5,399,497) teach first and second fluid reagents in a microchannel separated by a third fluid (air), which is immiscible with the first and second fluid reagents, but do not teach flowing a fluid sample over a surface of the microchannel and allowing sample components to bind with a binding partner disposed on the surface or accumulating an opaque material on the microfluidic channel.

6. Gallagher et al. (US 2003/0064507) teach flowing a fluid sample over a surface and allowing a sample component to bind with a binding partner on the surface of the channel, but fail to teach flowing in series in the microfluidic channel a predetermined sequence of fluid plugs including a first, second and third fluids, wherein the first and second fluids are separated by the third fluid which is immiscible with both the first and second fluids.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/  
Patent Examiner, Art Unit 1641